UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,330	01/29/2007	Joseph L. Witztum	00015-076US1/SD2003-2008-	6646

26138 7590 05/12/2011

Joseph R. Baker, APC
Gavrilovich, Dodd & Lindsey LLP
4660 La Jolla Village Drive, Suite 750
San Diego, CA 92122

EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
05/12/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,330	WITZTUM ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6 and 8-31* is/are pending in the application.

4a) Of the above claim(s) *15-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6,8-14,26-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/1/10 has been entered.

2. Claims 1, 2, 4-6 and 8-31 are pending.
Claims 15-25 stand withdrawn from further consideration by the examiner under 37 CFR 1.142 (b) as being drawn to a nonelected invention.

Claims 1, 2, 4-6, 8-14 and 26-31 are under consideration in the instant application.

3. The following rejection remains.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2, 4-6, 8-14 and 26-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 92/10203, of record, in view of U.S. Pat. No. 5,455,032, of record, and Shaw et al (J. Clnical. Invest., vol. 105, p. 1731-1740, IDS reference, of record) for the reasons set forth in the office action mailed on 1/6/10.

The '203 publication teaches administration of a vaccine composition comprising a phosphatidylcholine and an adjuvant (claims 1-24) in human and the vaccine composition treats atherosclerosis (abstract, claim 23-24, p. 1-3).

As is evidenced by Shaw et al. a phosphatidylcholine comprises two fatty acid chains and a phosphorylcholine headgroup (p. 1731, 2nd col.), the referenced vaccine composition comprising "phosphatidylcholine" includes a phosphorylcholine headgroup. Therefore, the claimed limitation of "phosphorylcholine enriched preparation" has been met.

Note that the claimed method recites administering a product made by a particular process. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by different process. *In re Thorpe,* 777 F.2d 695, 698, 227 USPQ 964 966 (Fed. Cir. 1985). See MPEP 2113. Given that the prior art composition and the recited product by process composition comprise phosphatidylcholine, the structural limitations of the administered composition have been met.

Where the claimed and prior art products are identical or substantially identical in structure or composition or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best* (562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the

applicant has the burden of showing that they are not. *In re Spada* (911 F.2d 705, 709, 15 USPQ 2d 1655, 1658 (Fed. Cir 1990). See MPEP 2112.01.

Given that the referenced and the recited "phosphorylcholine enriched preparation" appear to be identical from the evidence of record, the administration of the referenced composition is expected to result in the production of antibodies that bind to oxidized low density lipoprotein (oxLDL).

The disclosure of the '203 publication differs from the claimed invention in that it does not teach the use of phosphorylcholine derived from lipoteichoic acid of Spn as in claims 1 and 26 of the instant application.

The '032 patent teaches a method of vaccination with a composition comprising a phosphorylcholine (PC) and an adjuvant and the vaccination induces T15 antibody response (claims 1-19, col. 4-5). The '032 patent further teaches that the PC is the immunodominant epitope found on the surface of *Streptococcus pneumoniae* (Spn) and a polysaccharide of the cell wall component (lipoteichoic acid) is a major virulent factor of Spn (col. 4) and PC antibodies bind to Spn via the cell wall component. Moreover, the '032 patent teaches that the composition comprising PC provides immunization for pathogenic organisms having PC as a component of their cell wall capsids (col. 2).

Shaw et al. teach that T15 antibodies bind to various oxidized LDL (oxLDL) derived from 1-palmitoyl-2-oxovaleroyl-sn-glycero-3-phosphoryl-choline (POVPC) (p.1731). Shaw et al. further teach that T15 antibodies affect atherosclerosis by preventing foam-cell formation and deposition of oxidized LDL in the artery wall (p. 1739).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer PC preparation of lipoteichoic acid of Spn or from POVPC as taught by the '032 patent and Shaw et al. to inhibit atherogenesis.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because vaccinating with phosphorylcholine induces T15 antibody response and T15 antibody affects atherosclerosis by preventing foam-cell formation and deposition of oxidized LDL in the artery. Given that PC is an immunodominant epitope found on Spn and induces T15 antibody response which effectively removes oxidized LDL, using PC derived from a POVPC of Spn or lipoteichoic acid will provide more oxidation dependent epitopes (p. 1739).

Further, given that T15 antibodies affect atherosclerosis by preventing foam cell formation and deposition of oxidized LDL as per the teachings of Shaw et al., it would have been obvious to administer antibodies that bind oxidized lipoproteins such as the T15 antibodies of Shaw et al., to inhibit foam cell formation and oxLDL deposition. Thus, claims 9-12 have been included in this rejection.

From the teachings of references, it would have been obvious to one of ordinary skill in the art to combine the teachings of the references and there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 3/8/10 have been fully considered but they were not persuasive.

Applicant has asserted that the '203 publication does not teach immunizing a preparation from *Streptococcus* prevents atherogenesis results in the production of IgM and the '032 patent does not teach lipoteichoic acid. Applicant has further argued that the combination of the references does not result in the claimed invention.

Contrary to Applicant's assertion that the '032 patent does not teach lipoteichoic acid, the '032 patent teaches the use of the polysaccharide component of cell wall of *Streptococcus* that is detected by T15 antibody which specifically binds a phosphocholine (col. 4-5) moiety. As is defined by the specification of the instant application, lipoteichoic acid is a major cell wall component and phosphocholine moiety is a prominent constituent of lipoteichoic acid ([0012], p. 4). The T15 antibody specifically binds to phosphocholine moiety of cell wall polysaccharide. As such, the detection with T15 antibodies is a positive indication of lipoteichoic acid.

As discussed in the '032 patent, the T15 positive antigens from the *Streptococcus* demonstrated a higher immune response (col.4-5) and the polysaccharide portion of cell wall with phosphocholine is a major antigenic determinant. Therefore, the T15 positive phosphocholine portion of cell wall polysaccharide of *Streptococcus* is indeed a lipoteichoic acid and the claimed limitation has been taught by the '032 patent. Further, the IgM production is detected in the studies shown in the '032 patent (Tables 1-2).

Given that the '203 publication teaches the vaccine composition for treatment of atherosclerosis and the motivation to substitute the antigen with lipoteichoic acid is from the '032 patent, the combination of the references results in the claimed invention. One cannot show nonobviousness by attacking references individually where the rejection is based on combination of the references. See MPEP2145.

6. No claims are allowable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F, 9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
May 5, 2011

/Yunsoo Kim/
Primary Examiner, Art Unit 1644